



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

APR - 7 1999

0002 '99 APR 20 P2:13

Ms. Ona Scandurra  
Director of Nutritional Communications  
NBTY, Inc.  
90 Orville Drive  
Bohemia, New York 11716-2510

Dear Ms. Scandurra:

This is in response to your letter of March 30, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that NBTY, Inc. is making the following claims, among others, for the product Red Clover Menopausal Support Complex:

"...ease the discomfort associated with menopause"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that this product is intended to treat, prevent, cure, or mitigate disease, namely symptomatic disorders of menopause. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.  
Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

975-0163

LET 266

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Copies: -

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, New York District Office, Office of Compliance, HFR-NE140

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (r/f, File)

HFS-450 (r/f, File)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605 (Bowers)

GCF-1 (Dorsey)

HFV-228 (SBenz)

HFV-232 (ABrown)

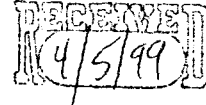
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90 Orville Drive, Bohemia, NY 11716-2510 • Phone: (516)244-2150 • Fax: (516) 244-2153

March 30, 1999

Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, SW (HFS-450)  
Washington, D.C. 20204



Dear Sir or Madam:

This letter will serve as a 30 day notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 that NBTY Inc. is using the following statement on Red Clover Menopausal Support complex and other supplements containing isoflavones under the following brand names: American Health, Body Fortress, Good 'N Natural, Health's Finest, Heartland, Herbal Authority, Hudson, Life's Finest, Natural Wealth, Nature's Bounty, Nutrition Headquarters, Puritan's Pride, Select Herbals, US Nutrition, Vitamin World:

- These isoflavones can help support the natural changes that occur in your body during midlife. Red Clover Menopausal Support Complex provides you with a natural way to ease the discomfort associated with menopause.

The above statements are accompanied by the required disclaimer pursuant to Section 6 of the Dietary Supplement Health and Education Act.

Sincerely,

A handwritten signature in cursive script that reads "Ona Scandurra".

Ona Scandurra, MS, RD  
Director of Nutrition Communications